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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,185	03/07/2001	Jochen G. Salfeld	BBI-043CPUSCN	1672
959	7590	02/09/2006	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/801,185	SALFELD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David A. Saunders, PhD	1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 114-121 and 141-166 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 114-121, 141-166 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1644

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 12/9/05 (amendment and IDS) have been entered.

The claims pending and under examination are 114-121 and 141-166.

The following corrections pertain to the previous Office action:

On PTO-326, under **Disposition of Claims**, claim 114 should have been indicated as allowed, rather than as rejected.

At page 2, claim 112, rather than claim 114, should have been included in the rejection under 112, first para.

At page(s) 3, line 2 “instead” should have read as –inserted--.

The amendment has overcome previously stated issues as follows:

The objection to claims 125, 127, and 131-133.

All rejections of claims under 35 USC 112, 1st paragraph, as set forth at pages 2-12.

The obviousness type double patenting rejections set forth at pages 12-13.

Throughout this action the examiner will refer to portions of applicant's disclosure by reference to paragraph numbers in square brackets, as they appear in the US Pre-Grant

Art Unit: 1644

Publication of this application. This publication is cited on attached Form PTO-892. Applicant's filed specification is of such length that the examiner does not have time to find the page and line numbers in the specification that correspond to the paragraph numbers in the pre-grant-publication. Any response that refers to applicant's disclosure should refer to paragraph numbers of the Pre-Grant Publication.

Upon reconsideration the following grounds of rejection are newly stated.

Claims 141-142 are 159-166 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36-40 and 49 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed by the issued claims.

Instant claim 141 parallels issued claim 36, except that instant claim 141 is limited to "treating a subject suffering from rheumatoid arthritis" while issued claim 36 is more broadly recited as treating a subject suffering from a disorder in which TNF.alpha is detrimental". The instant claims are clearly encompassed by the issued claims because a "disorder in which TNF.alpha is detrimental" clearly encompasses "rheumatoid arthritis", as shown by issued claims 40 (rheumatoid arthritis is an autoimmune disease) and 49.

In like manner instant claims 142 and 165-166 parallel issued claims 37-39.

Instant claims 159-163 are included because their recited off-rate constants and cytotoxicity values are within the range of the off-rate constants and cytotoxicity values recited in issued claim 36.

Regarding claim 164, the terms “recombinant antibody” and “antigen binding portion thereof” are not recited in the copending claims; however, what has been disclosed as the D2E7 antibody is a recombinant antibody (see para. [0008]). Also, the “antigen binding portion” of the disclosed antibodies has been disclosed throughout, as being functionally equivalent to the whole antibodies and therefore not patentably distinct.

Claims 114-121 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 and 36-39 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed by the issued claims.

Instant claim 114 parallels issued claim 4, except that instant claim 114 narrowly recites “inhibiting TNF.alpha activity in a human subject suffering from periodontal disease” while issued claim 4 more broadly recites “inhibiting TNF.alpha activity in a human subject suffering from a disorder in which TNF.alpha activity is detrimental”. However, the instant claims would be read as being encompassed by the issued claim because the term “a disorder in which TNF.alpha activity is detrimental” encompasses “periodontal disease” as recited at para. [0147].

In like manner instant claims 115-117 parallel and are encompassed by issued claims 5-7.

Instant claim 118 parallels issued claim 36, except that instant claim 118 is limited to “treating a subject suffering from periodontal disease” while issued claim 36 is more broadly recited as treating a subject suffering from a disorder in which TNF.alpha is detrimental”. The instant claims are clearly encompassed by the issued claims because a “disorder in which TNF.alpha is detrimental” clearly encompasses “periodontal disease” as recited in para [0147].

Likewise, instant claims 119-121 parallel and are encompassed by issued claims 37-39.

Claims 143-150 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 and 36-39 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed by the issued claims.

Instant claim 143 parallels issued claim 4, except that instant claim 143 narrowly recites “inhibiting TNF.alpha activity in a human subject suffering from obesity” while issued claim 4 more broadly recites “inhibiting TNF.alpha activity in a human subject suffering from a disorder in which TNF.alpha activity is detrimental”. However, the instant claims would be read as being encompassed by the issued claim because the term “a disorder in which TNF.alpha activity is detrimental” encompasses “obesity” as recited at para. [0147].

In like manner instant claims 144-146 parallel and are encompassed by issued claims 5-7.

Instant claim 147 parallels issued claim 36, except that instant claim 147 is limited to “treating a subject suffering from obesity” while issued claim 36 is more broadly recited as treating a subject suffering from a disorder in which TNF.alpha is detrimental”. The instant claims are clearly encompassed by the issued claims because a “disorder in which TNF.alpha is detrimental” clearly encompasses “obesity” as recited in para [0147].

Likewise, instant claims 148-150 parallel and are encompassed by issued claims 37-39.

Claims 151-158 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 and 36-39 of U.S. Patent No. 6,509,015.

Art Unit: 1644

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed by the issued claims.

Instant claim 151 parallels issued claim 4, except that instant claim 151 narrowly recites “inhibiting TNF.alpha activity in a human subject suffering from radiation toxicity” while issued claim 4 more broadly recites “inhibiting TNF.alpha activity in a human subject suffering from a disorder in which TNF.alpha activity is detrimental”. However, the instant claims would be read as being encompassed by the issued claim because the term “a disorder in which TNF.alpha activity is detrimental” encompasses “radiation toxicity” as recited at para. [0147].

In like manner instant claims 152-154 parallel and are encompassed by issued claims 5-7.

Instant claim 155 parallels issued claim 36, except that instant claim 155 is limited to “treating a subject suffering from radiation toxicity” while issued claim 36 is more broadly recited as treating a subject suffering from a disorder in which TNF.alpha is detrimental”. The instant claims are clearly encompassed by the issued claims because a “disorder in which TNF.alpha is detrimental” clearly encompasses “radiation toxicity” as recited in para [0147].

Likewise, instant claims 156-158 parallel and are encompassed by issued claims 37-39.

Applicant's arguments with respect to claims 114-121 and 141-166 have been considered but are moot in view of the new ground(s) of rejection.

On form PTO-1449 references C4 and C11 have been lined out because they are illegible.

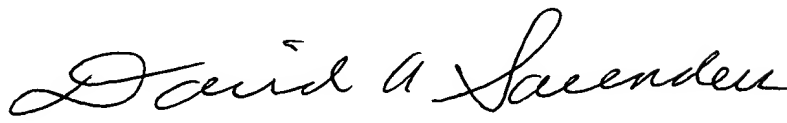
Art Unit: 1644

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 2/6/06 DAS

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182-1644